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09/449,270	11/24/1999	DAVID HARTLEY	PA-5169-CON	6069

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EXAMINER

HO, UYEN T

ART UNIT PAPER NUMBER

3731

DATE MAILED: 04/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/449,270

Applicant(s)

HARTLEY ET AL.

Examiner

(Jackie) Tan-Uyen T. Ho

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 13 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-63 is/are pending in the application.
- 4a) Of the above claim(s) 12-17 and 43-63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 18-42 is/are rejected.
- 7) ☒ Claim(s) 5-8 and 18-23 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 March 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2, 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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## DETAILED ACTION

### *Election/Restrictions*

200  
12/14/12  
12/12/12

1. Claims 14, 15 and 17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a ~~no~~elected species (depending on a ~~no~~elected claim), there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7. Also claims 18-23 which depend on claims 14-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a ~~no~~elected species (depending on a no elected claims 14-17).

### *Drawings*

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "23" has been used to designate both aperture in figure 9 and a portion of trigger wire in figure 8. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: "19," page 14, line 15. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

***Claim Objections***

4. Claim 18 is objected to because of the following informalities: "whilst the latter is" should be deleted. Appropriate correction is required.
5. Claims 5-8, 19-23 depending on claims 4-7 and 18-22 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim~~s~~ cannot depend from another multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 5-8, 19-23 depending on claims 4-7 and 18-22 are not been further treated on the merits.
6. Claim 23 is objected to because of the following informalities: "the introducer" should be "the arrangement". Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
8. Claim s 27-28 recites the limitation "the thin walled metal tube" in line 2 of claim 27 and in line 3 of claim 28. There is insufficient antecedent basis for this limitation in the claim.
9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
10. Claims 1-11, 18-42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as

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to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification fails to disclose in such a way as to enable one skilled in the art to make or use control members of an introducer for controlling position of the proximal and distal portions of a prosthesis. The specification fails to described how triggers wires secured the prosthesis to a distal end portion of the introducer or sleeve 10 and how the trigger wire are detached from the introducer in order to position of distal and proximal portions of the prosthesis at a desired site in a body lumen, as claimed.

***Claim Rejections - 35 USC § 102***

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

12. Claims 1-11, 18-26, 29-42 are rejected under 35 U.S.C. 102(e) as being anticipated by Quiachon et al. (5,628,783).

In regard to claims 1-8, Quiachon et al. disclose an introducer including:

- a prosthesis positioning mechanism comprising:
  - a distal attachment region having a distal attachment device (93),
  - a proximal attachment region having a proximal attachment device (132),
  - a control arrangement or a rotational arrangement (131),
- a first control member (86);
- a second control member (97);
- an expansion control mechanism (160).

In regard to claims 9-11, 18-23, Quiachon et al. disclose a device including:

- control sections (53, 54);
- a prosthesis positioning mechanism including:
  - a distal region having means (90) for controlling a distal end of a prosthesis,
  - a proximal region having means (130) for controlling a proximal end of the prosthesis,
  - a control or rotational arrangement (131),
- a first member (131) extending from the control section to the proximal region of the prosthesis positioning mechanism;
- a second member (206) extending from the control section to the distal region of prosthesis positioning mechanism;
- contraction and expansion means including a tubular member (160);

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- releasing mechanisms (113) in the control section;
- an expansion control mechanism (93).

In regard to claims 24-26, 29-42, Quiachon et al. disclose an introducer including:

- a proximal attachment device (90):
  - mounted on a flexible thin walled tube (61),
    - thin flexible tube having fluid connection means (74)
  - having a long flexible extension (80),
- a distal attachment device (131) mounted on a flexible thick walled tubing,
- proximal releasing means (86),
- distal releasing means (97),
- a haemostatic seal (167);
- means for introduce a medical agent (150);
- a proximal trigger wire (56);
- a distal trigger wire (91);
- an external sheath (160) having a tapered end;

### ***Conclusion***

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Baker et al. (6,345,118 & 5,693,083) and Quiachon et al. (5,957,973) disclose an introducer for deploying prosthesis.

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14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to (Jackie) Tan-Uyen T. Ho whose telephone number is (703) 306-3421. The examiner can normally be reached on MULTIFLEX Mon. to Sat..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on (703) 308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



(Jackie) Tan-Uyen T. Ho  
April 19, 2002



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